

**EVALUATION OF THE APPLICATION SUBMITTED ON BEHALF OF SOUTHWEST
WASHINGTON MEDICAL CENTER PROPOSING TO ESTABLISH A NEONATAL
INTENSIVE CARE NURSERY AND LEVEL III OBSTETRIC SERVICES AT THE HOSPITAL**

PROJECT DESCRIPTION

Health Systems Group is a Washington non-profit corporation, and the sole member of Southwest Washington Medical Center (SWMC). SWMC is a Washington private, not-for-profit corporation and a 501(c)(3) exempt organization. SWMC is a hospital located at 400 Northeast Mother Joseph Place in the city of Vancouver, within Clark County. SWMC provides Medicare and Medicaid acute care services at the following two sites under a single hospital license.

Southwest Washington Medical Center	400 Northeast Mother Joseph Place, Vancouver
Memorial Health Center ¹	3400 Main Street, Vancouver

SWMC is currently licensed for 360 acute care beds,² holds a three-year accreditation from the Joint Commission on Accreditation of Health Care Organizations, and is designated as a level II trauma hospital and trauma rehabilitation hospital.

Additionally, SWMC operates a Medicare certified hospice agency, known as Hospice Southwest, and Hospice Southwest operates a 20 bed hospice care center. Both facilities are also located in the city of Vancouver. [source: CN historical files]

Currently, SWMC has a special care nursery within space at the hospital that provides a full range of maternal and neonatal services for uncomplicated patients and for the majority of complicated obstetrical problems. For CN purposes, this service is known as "level II obstetric services" or simply "level II services." [source: Application, Executive Summary]

This application proposes to establish a neonatal intensive care unit (NICU) and level III obstetric services within space at SWMC. A level III obstetric service is offered in an area designed, organized, equipped, and staffed to provide services to the few women and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Such a service provides the coordination of care, communication, transfer, and transportation for level III patients in a given region. Level III services include the provision of leadership in preparatory and continuing education in prenatal and perinatal care and may be involved in clinical and basic research. Hereinafter, the proposed program will be referred to as "level III services." [source: Washington Administrative Code 246-310-020]

SWMC has already made the capital and operating investments to expand and remodel its current 10-bed level IIB special care nursery. The special care nursery remodel was primarily funded through a \$2.4 million philanthropic donation. The remodel allows SWMC to expand the special care nursery from 10 to 18 beds. This expansion would accommodate the proposed level III services, and allow SWMC to provider services for a total of 18 level II or III infants. [source: Application, Executive Summary]

¹ Only psychiatric beds are located at the Memorial Health Center site.

² On April 8, 2002, SWMC was issued CN #1241 approving the addition of 82 beds to the existing 360 acute care beds, for a facility total of 442 acute care beds. As of the writing of this evaluation, SWMC has not implemented CN #1241.

SWMC has partnered with Oregon Health & Science University (OHSU) and Oregon Health & Science University Medical Group (OHSUMG) for this project. SWMC states that combining efforts of OHSU and OHSUMG with the hospital will assist SWMC with the operations of its current level II services and development of the proposed level III services. [source: Application, p6]

If this project is approved, SWMC anticipates its level III services would be offered within one year of approval. [source: Application, p9] Under this timeline, year 2008 would be SWMC's first full calendar year of operation as a level III provider. At project completion, SWMC would have the capacity for 18 infants requiring either level II or level III services. [source: Application, Executive Summary]

The capital expenditure associated with the establishment of SWMC's proposed level III services is \$50,000, which includes only the fees for submission of the application. [source: Application, p29] This project does not propose to increase the total acute care licensed bed capacity at SWMC, within Clark County, or within Washington State as a whole.

APPLICABILITY OF CERTIFICATE OF NEED LAW

This project is subject to Certificate of Need review as the establishment of a new tertiary health service under the provisions of Revised Code of Washington (RCW) 70.38.105(4)(f) and Washington Administrative Code (WAC) 246-310-020(1)(d)(i)(C).

APPLICATION CHRONOLOGY

July 28, 2005	Letter of Intent Submitted
September 22, 2005	Application Submitted
September 23, 2005, through January 2, 2006	Department's Pre-Review Activities <ul style="list-style-type: none">• 1st screening activities and responses• 2nd screening activities and responses
January 3, 2006	Department Begins Review of the Application <ul style="list-style-type: none">• public comments accepted throughout review• no public hearing requested or conducted
March 7, 2006	Rebuttal Documents Submitted to Department
April 21, 2006	Department's Anticipated Decision Date
April 21, 2006	Department's Actual Decision Date

AFFECTED PERSONS

Throughout the review of this project, one entity sought and received affected person status under WAC 246-310-010--Legacy Health System on behalf of Legacy Salmon Creek Hospital located in Vancouver within Clark County.

SOURCE INFORMATION REVIEWED

- Southwest Washington Medical Center's Certificate of Need Application received September 22, 2005
- Southwest Washington Medical Center's supplemental information dated November 18, 2005, January 11, 2006, and January 19, 2006
- Legacy Health System's November 11, 2005, response to the department's October 12, 2005, request for information
- Comments provided throughout the review of the project provided until February 8, 2006
- Legacy Health System's rebuttal comments received March 7, 2006
- Southwest Washington Medical Center's rebuttal comments received March 6, 2006³
- Comprehensive Hospital Abstract Reporting System (CHARS) data obtained from the Department of Health's Office of Hospital and Patient Data Systems
- Financial feasibility and cost containment evaluation prepared by the Department of Health's Office of Hospital and Patient Data Systems (April 3, 2006)
- Historical charity care data obtained from the Department of Health's Office of Hospital and Patient Data Systems (2002, 2003, and 2004 summaries)
- Population data obtained from the Office Financial Management based on year 2000 census published January 2002.
- Licensing and/or survey data provided by the Department of Health's Office of Health Care Survey
- Emergency and trauma designation data provided by the Department of Health's Office of Emergency Medical and Trauma Prevention
- Washington State Perinatal Levels of Care Criteria adopted by the Perinatal Advisory Committee-February 2005, used as guidance
- Data obtained from the Internet regarding health care worker shortages in Washington State
- Data obtained from the Internet regarding Southwest Washington Medical Center's project
- Data obtained from the Internet regarding mileage and distance
- Certificate of Need Historical files

CRITERIA EVALUATION

To obtain Certificate of Need approval, Southwest Washington Medical Center must demonstrate compliance with the criteria found in WAC 246-310-210 (need); 246-310-220 (financial feasibility); 246-310-230 (structure and process of care); and 246-310-240 (cost containment).⁴

CONCLUSION

For the reasons stated in this evaluation, the application submitted on behalf of Southwest Washington Medical Center proposing to establish a neonatal intensive care unit (NICU) and level III obstetric services within space at the hospital is not consistent with applicable criteria of the Certificate of Need Program, and a Certificate of Need should be denied.

³ Included within SWMC rebuttal documents is a letter addressed to the department from OHSU; given that OHSU did not obtain affected person status, this letter was submitted inappropriately and therefore, not considered in this review.

⁴ Each criterion contains certain sub-criteria. The following sub-criteria are not discussed in this evaluation because they are not relevant to this project: WAC 246-310-210(3), (4), (5), and (6); and WAC 246-310-240 (2) and (3).

A. Need (WAC 246-310-210)

Based on the source information reviewed, the department determines that the applicant has not met the need criteria in WAC 246-310-210.

- (1) The population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need.

WAC 246-310-020 states (in summary) that a level III obstetric service is to be in an area designed, organized, equipped, and staffed to provide services to the few women and infants requiring full intensive care services for the most serious type of maternal-fetal and neonatal illnesses and abnormalities. Such a service provides the coordination of care, communication, transfer, and transportation for level III patients in a given region. Level III services include the provision of leadership in preparatory and continuing education in prenatal and perinatal care and may be involved in clinical and basic research.

Level III services are considered tertiary services as defined by WAC 246-310-010. For some tertiary services, such as open heart surgery, the department uses an established methodology to assist in its evaluation of need for the services. For other tertiary services, including level III services, no such methodology exists. Given that the department has not developed an established methodology for level III services, an evaluation of the need criterion begins with an evaluation of the methodology provided by the applicant.

Southwest Washington Medical Center Rationale for Level III Services

The applicant used historical Comprehensive Hospital Abstract Reporting System (CHARS) data to assist in demonstrating need for a level III service. CHARS data is reported by each Washington State hospital to the department's Office of Hospital and Patient Data Systems. The CHARS data provides historical trends in discharges and lengths of stay for newborn patients for the major diagnostic category (MDC) #15 - NEWBORNS AND OTHER NEONATES WITH CONDITIONS ORIGINATING IN THE PERINATAL PERIOD. MDC #15 is made up of seven diagnosis related groups (DRGs)--385 through 391. The chart below provides the DRG and corresponding definition for MDC #15.⁵

DRG	Definition	Level of Care
385	NEONATES, DIED OR TRANSFERRED TO ANOTHER ACUTE CARE FACILITY	Level III
386	EXTREME IMMATUREITY OR RESPIRATORY DISTRESS SYNDROME, NEONATE	Level III
387	PREMATURITY WITH MAJOR PROBLEMS	Levels II or III
388	PREMATURITY WITHOUT MAJOR PROBLEMS	Level II
389	FULL TERM NEONATE WITH MAJOR PROBLEMS	Level II
390	NEONATE WITH OTHER SIGNIFICANT PROBLEMS	Levels I or II
391	NORMAL NEWBORN	Level I

As shown in the chart above, of the DRGs included in MDC #15, some do not correspond exactly with the level of care definitions. However, the majority of level III patients are included in DRGs 385 and 386, with a few level III patients in DRG 387.

To support its establishment of level III services, SWMC provided the following rationale for this project:

⁵ Each DRGs corresponding level of care is based on October 3, 2001, testimony provided by Louis Pollack, MD, a board certified neonatologist and member of Washington State Perinatal Advisory Committee.

“Clark-Skamania county service area births have grown dramatically in each of the three levels of care. There is no level III NICU service for the Cowlitz-Wahkiakum service area. Based on the current and projected population of the service area; the defined need for 17-21 level II and III beds, and the combined projected capacity of a total for 33 SPN [special care nursery] beds (15 at Legacy Salmon Creek and 18 at SWMC) to serve level I to III neonates; there will be an ongoing shortage of beds to serve the total projected nursery population within the service area. In short, the project proposed is not duplicative and will only assist in meeting the basic needs of residents in the service area. SWMC is the 2nd largest neonatal delivery system in Washington State. Over 5,000 deliveries a year occur at SWMC. As discussed earlier in this application and in SWMC’s Level of Care service delivery plan [provided in Appendix 10 of the application], the differences in Level IIB and Level IIIA can be quite subtle. Without a Level IIIA NICU service located at SWMC, SWMC is placed in the position of having to transfer neonates from SWMC to other NICU centers in Portland outside of the Clark-Skamania service area or to the Legacy Salmon Creek Hospital when it is able to accommodate NICU Level III patients. SWMC recognizes that by providing Level III services we would be able to avoid transferring patients which results in additional costs, medical risk to infants, and stress on families without evidenced-based improvement in health care outcome or cost reduction. SWMC is the primary provider of maternal, neonatal and early pediatric care for the medically indigent families in our service area. If our overall maternal fetal market share is degraded it will impact our ability to provide a full range of services to the medically indigent in our service area” [source: Application, p15]

Using the two-county service area of Clark and Skamania, SWMC provided a table to show the historical and projected number of newborn discharges and days, by level of care. [source: Application, p20, Table 10] SWMC also provided historical and projected population and birth projections data for Clark, Skamania, Cowlitz, and Wahkiakum counties. [source: Application, Appendix 9] Within the application, SWMC identified a total of four providers--three in Portland and one in Vancouver--that currently provide level III services to the residents of Clark, Skamania, Cowlitz, and Wahkiakum counties. The four facilities are:

Facility	City/State
Legacy Emanuel Hospital and Health Center	Portland, Oregon
Oregon Health & Sciences Hospital and Clinics	Portland, Oregon
Providence St. Vincent Medical Center	Portland, Oregon
Legacy Salmon Creek Hospital	Vancouver, Washington

To assist in a demonstration of need for this project, SWMC provided a travel analysis from SWMC to each of the four level III providers identified above based on “a.m. peak travel time.” The travel time analysis provided historical year 2000 and projected year 2025. [source: Application, p18]

To further demonstrate its need for level III services at SWMC, the applicant provided a table showing costs associated with the transport of patients from SWMC to the four providers. For each of the providers, SWMC estimated the costs associated with the transport ranged from \$4,396 to \$4,462 per patient, per transport. [source: November 18, 2005, supplemental information, pp70-74]

SWMC also provided extensive discussion to demonstrate that a new level III service at SWMC would not be a duplication of services in the county. Below is an excerpt of SWMC’s discussion. [source: Application, pp15-16; November 18, 2005, supplemental information, p76]

“DOH reached a finding in the Legacy and SWMC comparative review that a level of outflow exceeding 5% demonstrated need from both an access and availability standpoint for additional hospital beds to serve Washington State patients. Legacy Health System in its comparative review testimony and submission indicated that use of Portland NICU tertiary services created a stress on the existing system of care in the Portland area. A number of families testified to the stress that transfer of infants requiring Level III NICU services created. While Legacy Salmon Creek is approved and intends to establish Level III NICU services, the facility will not meet all of the Level II and Level III NICU services within the Clark-Skamania service area. Finally, there is the issue of choice which plays a significant role in whether the department approves new hospitals. Patients and families will benefit when they have a choice as long as there is sufficient volume to support two facilities. The SWMC utilization projections and the OFM [Office of Financial Management] mid-range birth projections for the Clark-Skamania service area demonstrate that sufficient volume will be generated by the service area population to support 33 neonatal nursery beds. Even if the department were to conclude that consumer choice now plays no role in the Certificate of Need decisions, there is the issue of provider contracting. Clark-Skamania County service area births have grown dramatically in each of the three levels of care and there is no level III NICU service in the Cowlitz-Wahkiakum service area. The service area needs the combined capacity of two Level III NICU services to meet the growing capacity requirements generated by the Clark Skamania service area.”

As stated in the project description portion of this evaluation, SWMC has entered into an “Administrative Services Agreement” (Agreement) with Oregon Health & Science University (OHSU) and Oregon Health & Science University Medical Group (OHSUMG) for this project. Under the Agreement, OHSU and OHSUMG will provide medical director services through a physician employee to be responsible for SWMC’s current level IIB and its proposed level III services. The Agreement further outlines the roles and responsibilities for each of the entities; for the current level IIB service, the Agreement includes back-transport of level IIB neonates from a Portland hospital to SWMC as soon as the patient is medically stable and able to be supported by family and the care providers. [source: Application, p6; November 18, 2005, supplemental information, pp9-25]

Using the rationale described above, SWMC provided the total number of level III patients--based on DRGs 385 and 386--projected to occur in the Clark-Skamania service area for years 2007 through 2010. Using the total number of patients projected, SWMC projected the total number of combined level II and level III beds needed to serve both level II and level III patients. Those projections are shown in Table 1 below. [source: Application, pp20-22]

Table 1
Clark-Skamania County Projected Level III Activity

	Projected 2007	Year 1--2008	Year 2--2009	Year 3--2010
Total # of level I patients	4,993	5,122	5,256	5,392
Total # of level I patient days	9,117	9,354	9,597	9,847
Total # of level II patients	911	935	959	984
Total # of level II patient days	2,983	3,061	3,141	3,222
Total # of level III patients	287	294	302	310
Total # of level III patient days	4,267	4,378	4,492	4,609
Total # of beds needed for both level II and level III patients	25	26	27	28

As shown in Table 1 above, SWMC projects the combined counties of Clark and Skamania would require 25 combined level II and level III beds to adequately serve the projected number of patients in year 2007. The projected number of beds increases to 28 by the end of year 2010.

Using the two-county projections shown in Table 1 above, SWMC provided the facility projections for its level III services summarized in Table 2 below. [source: Application, pp20-22; November 11, 2005, supplemental information, p64]

Table 2
Southwest Washington Medical Center's Projected Level III Activity

	Projected 2007	Year 1--2008	Year 2--2009	Year 3--2010
SWMC # of patients	163	168	173	178
SWMC # of patient days	1,630	1,848	2, 076	2,136
SWMC market share of total patients	57%	57%	57%	57%
SWMC average length of stay	10 days	11 days	12 days	12 days
SWMC average daily census	5.1	5.1	5.7	5.9

When comparing SWMC's projections shown in Tables 1 and 2 above, SWMC anticipates it would capture 57% of the projected level III market in the two county area, which equates to 168 level III admissions in year one, and an anticipated 3% increase of patients for each of the projected years through year 2010. SWMC provided its calculations to determine its projected market share and provided the following rationale for anticipating it would capture the majority of the level III patients. [source: Application, p26]

"The market share percentages seem reasonable based on the following: region specific experience shows that the number of level II neonates have increased at a higher rate than historical birth rates from 1999-2004; OFM mid-range population and birth projections are lower than the actual experience in the region; SWMC projections are approximately 3% higher than OFM/COMPDATA projections because SWMC is looking at all counties in its service area, not just Clark and Skamania counties; and future market share was estimated taking into account "protected markets" covered by contracts and estimated gains resulting from providing level II-III services"...It is estimated that SWMC will maintain this market share as long as it provides full services."

The current provider of level III services in Clark County--Legacy Salmon Creek Hospital (LSCH)--provided comments regarding this project. Below is a summary of LSCH's concern(s) related to need criteria under WAC 246-310-210 and SWMC's responses to those concerns.

Legacy Salmon Creek Hospital Public Comment

"...Legacy received Washington State Department of Health Certificate of Need approval in March of 2002 to establish a NICU as part of its new Clark County hospital. ...The 25 bed unit opened in late August 2005. As of January 1, 2006, the unit is fully operational and currently accepts neonates with gestational ages of \geq 28 weeks. We expect to begin admitting all infants, regardless of gestational age within the next several months." [source: February 6, 2006, comments, p2]

LSCH asserts that there is no quantifiable need for an additional level III service in Clark County, and SWMC's projected need is based on the following incorrect or erroneous assumptions:

- 1) DRG 387 has historically been included in the level II category; SWMC included DRG 387 within its level III projections which results in an overestimation of need for level III services.
- 2) SWMC overstates the possible retention rates and double counts volume that has already been approved for LSCH.
- 3) SWMC understates the existing capacity at LSCH.
- 4) LSCH is available and accessible to accommodate future [level III] demand.
[source: February 6, 2006, comments, pp5-11]

Southwest Washington Medical Center Response

[source: SWMC March 3, 2006, rebuttal documents, pp1-13]

- There is sufficient need projected to support both Legacy Salmon Creek and SWMC level III NICU services.
- SWMC has an inborn neonatal volume of 5,054 deliveries in FY 2005 and is on target for 4,200 deliveries in FY 2006 which supports the establishment of level III services.
- SWMC already meets the criteria advised by the Washington State Perinatal Guidelines stating that those facilities providing level III services should have a minimum combined average daily census of 10 level II and level III neonates even though it currently provides only level II care.
- Need projections are based on level II and level III combined, not level III alone which is consistent with all CON applications and the delivery of level III services.
- The use of 95% retention rate per the DOH methodology as applied to total bed determination for two medical centers in Vancouver is the appropriate standard to be used in the NICU calculation and is an achievable and appropriate target.
- SWMC has not underestimated the NICU beds at LSCH.
- SWMC and LSCH are relying on different patient referral channels and, therefore, the SWMC level III NICU will have minimal impact on Legacy's stated strategy to build volumes in their NICU.
- There is not a duplication of services due to the changing Washington State Perinatal Level of Care Guidelines that make the differences in care for a level IIB and a level IIIA neonate very subtle.
- SWMC redesigned their special care nursery to serve their existing neonatal population. SWMC did not build a new NICU.

Before evaluating SWMC's project, the department must first determine the service area of the project and current capacity and level of care provided in the service area.

Department's Determination of Service Area

SWMC defines its service area to be Clark and Skamania counties. SWMC also states that patients residing in Cowlitz and Wahkiakum counties do not have ready access to level III services and would be able to access level III services at SWMC. [source: Application, pp16-17]

Level III services are included within the description of tertiary services in WAC 246-310-020(1)(d)(i)(C). Tertiary health service is defined in WAC 246-310-010 as "a specialized service meeting complicated medical needs of people and requires sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." For these reasons, level III services are not, and should not be, offered in every hospital within the state, nor should they be

limited to a given service area. With a tertiary service, it is expected that a patient will be transported some distance to receive quality care from a quality provider. WAC 246-310-010 defines health service area as “a geographic region appropriate for effective health planning including a broad range of health services.” Using the definitions for both tertiary service and health service area, the department can conclude that the service area identified by an applicant for level III services is expected to include at least an entire county, and generally includes neighboring counties if the tertiary service under review is not already provided in those counties. For this project, it is reasonable to include Clark County within the level III service area. The inclusion of Cowlitz, Skamania, and Wahkiakum counties within the service area is determined by reviewing SWMC’s historical patient discharges for years 2000-2004. A summary of SWMC’s MDC #15 discharges for the four counties is shown in Table 3 below. [source: CHARS data years 2000-2004]

Table 3
Southwest Washington Medical Center’s 2000-2004 # of Discharges for MDC #15

	SWMC Totals	Clark	Cowlitz	Skamania	Wahkiakum
Year 2000	4,796	4,586	119	16	0
Year 2001	4,768	4,569	115	10	0
Year 2002	4,739	4,504	123	15	1
Year 2003	4,851	4,603	133	18	0
Year 2004	5,057	4,745	159	13	0

As shown in Table 3 above, as expected, the vast majority of SWMC’s MDC #15 Washington State patients originate from Clark County--the five year percentage ranges from 94% to 96% of SWMC’s total patients originate from Clark County. SWMC’s Cowlitz County five year percentages range from 2% to 3%. While these percentages are low when compared to SWMC’s total discharges for MDC #15, given that Cowlitz and Clark County are neighboring counties and a number of Cowlitz County OB patients are admitted into SWMC, it is reasonable to consider Cowlitz County as part of SWMC’s MDC #15 service area.

Table 3 shows Skamania County’s five year percentages range from 0.2% to 0.3%. A review of hospital discharge data obtained from the Oregon Department of Human Services, reveals that a large number of Skamania County residents choose to obtain health care in Oregon. [2004 Skamania/Oregon data provided by OHPDS] As a result, Skamania County would not be considered part of SWMC’s MDC #15 service area.

Table 3 shows Wahkiakum County patients typically do not travel to SWMC for MDC #15 services. Therefore, Wahkiakum County would not be considered part of SWMC’s MDC #15 service area. In summary, it is reasonable to conclude that SWMC’s MDC #15 service area is Clark and Cowlitz counties.

Determination of Current Capacity and Level of Care Currently Provided in the Service Area

The following acute care hospitals are located in the combined counties of Clark and Cowlitz:

- St. John located in Cowlitz County;
- LSCH located in Clark County; and
- the applicant, SWMC, located in Clark County.

All three hospitals provide level I and level II OB services, which typically include DRGs 388 - 391, with portions of DRG 387. Currently, LSCH is the only provider of level III services. Department

files do not identify the number of level II beds in operation at St. John. Within its application, SWMC states its special care nursery houses 10 level II beds. [source: Application, p8] LSCH received CN approval to establish its level III services at the same time it received approval to establish the hospital. [source: Evaluation for CN #1263 issued to Legacy Health System] Within the LSCH application, the applicant and department acknowledge the combined level II/III services would house 25 beds. As a result, the two-county service area's current capacity is at least 11 dedicated level II beds and 25 combined level II/III beds, for a combined capacity of at least 36 level II and III beds.⁶

SWMC provided a population based methodology that concludes need for 17-21 level II and III beds, and the combined projected capacity of a total for 33 SPN [special care nursery] beds to serve level I to III neonates. [source: Application, p15, 20-22] The department notes that SWMC bases its methodology on Clark and Skamania counties, rather than Clark and Cowlitz counties. As a result, SWMC's methodology includes populations and projections for Skamania County. Given that the department does not concur with SWMC that Skamania County would be considered part of SWMC's level III service area, the conclusion of need for 17-21 level II and III beds, and the combined projected capacity of a total for 33 SPN [special care nursery] beds to serve level I to III neonates is overstated. If Cowlitz County, rather than Skamania County had been included in SWMC's methodology projections, SWMC may have determined a need for more than the combined capacity of 33 SPN beds; however, SWMC would also have to address any current capacity at St. John in Cowlitz County.

Even if the department were to accept SWMC's need methodology as presented, the current capacity of the Clark County alone (35 level II / III beds) is more than concluded by SWMC to be needed for the combined counties of Clark and Skamania (17-21 level II and III beds).

SWMC states that there is sufficient need projected to support two level III services within Clark County, and approval of this project would not be a duplication of services. LSCH opened on August 15, 2005⁷--39 days before SWMC submitted this project. LSCH began admitting patients into its neonatal intensive care unit (NICU) on August 22, 2005--32 days before SWMC submitted this application. While LSCH's NICU is fully operational and accepting level III patients, it began by limiting admissions to infants with gestational ages ≥ 30 weeks, and gradually worked toward admissions of infants with gestational ages ≥ 28 weeks. [source: LSCH November 11, 2005, public comment] For level III services, this gradual, phased-in approach is generally the approach used by hospitals. This approach allows the NICU staff to build on education and skills, while consistently monitoring outcomes and making any adjustments as necessary; this is an approach that the department would expect. As of the writing of this evaluation, LSCH's hospital and NICU has been accepting patients for only approximately 8 months, as a result, LSCH has not reached nearly enough sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care. SWMC has failed to demonstrate that the current provider of level III NICU services, also located in Vancouver, is neither available nor accessible. It would be unreasonable to approve a second level III NICU in the same service area when the first level III NICU has been in operation for less than a year. Such an approval would jeopardize the current provider from reaching utilization levels to optimize provider effectiveness and assure quality of care. In conclusion, the department recognizes that allowing LSCH to reach sufficient patient volumes is essential, and SWMC has failed to demonstrate that establishment of its level III services would not be an

⁶ To reach a capacity of 36 beds, the department is counting at least level II beds at St. John.

⁷ LSCH press release dated August 5, 2005.

unnecessary duplication of services in Clark County. The department therefore concludes that approval of SWMC's level III services would be an unnecessary duplication of services.

Travel and Costs

As part of its demonstration of need for an additional level III service in Clark County, SWMC provided a travel time analysis from SWMC to the existing level III providers in the county--LSCH--and three Portland, Oregon providers--Oregon Health & Sciences Hospital; Providence St. Vincent Medical Center, and Legacy Emanuel Hospital. [source: Application, p18] Additionally, SWMC provided a table shows costs associated with the transport of level III patients to the four providers. [source: November 18, 2005, supplemental information, pp70-74] SWMC asserts that the costs to transport a patient from SWMC to any of the four providers in Vancouver or Portland ranges from \$4,396 to \$4,462 per patient, per transport. Under the Agreement between SWMC and Oregon Health & Science University (OHSU) and Oregon Health & Science University Medical Group (OHSUMG), SWMC transports its patients to one of the Portland area hospitals. Other than this agreement, SWMC does not provide any other rationale for transporting its patients to Portland, rather than the closest level III facility in Vancouver--LSCH.

As previously stated in this evaluation, level III services are included in the definition of "tertiary services" defined by WAC 246-310-010. As a tertiary service, level III services meet the complicated medical needs of people and require sufficient patient volume to optimize provider effectiveness, quality of service, and improved outcomes of care." For these reasons, level III services are not, and should not be, offered in every hospital within the state. With a tertiary service, it is expected that a patient will be transported some distance to receive quality care from a quality provider. As a result, neither argument is relevant to this project.

In conclusion, SWMC has not demonstrated that the population served or to be served has need for the project and other services and facilities of the type proposed are not or will not be sufficiently available or accessible to meet that need as required in WAC 246-310-210. This sub criterion is not met.

- (2) All residents of the service area, including low-income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly are likely to have adequate access to the proposed health service or services.

To demonstrate compliance with this sub-criterion, SWMC provided a copy of its current admission and charity care policies for the hospital. [source: Application, Appendices 11 & 12]

The Admission Policy provides the overall guiding principles of the facility as to the types of patients that are appropriate candidates to use the facility and any assurances regarding access to treatment. All residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently have access to services at SWMC. The addition of level III services to the hospital is not expected to change this access. Additionally, the Admission Policy states that any patient requiring services at SWMC will be accepted to any SWMC healthcare facility without regard to race, color, ethnicity, religious beliefs, political beliefs, or ability to pay. [source: Application, Appendix 12]

To determine whether low income residents would have access to the services at SWMC, the department uses the facility's Medicaid eligibility or contracting with Medicaid as the measure to make that determination. To determine whether the elderly would have access to the hospital, the

department uses Medicare certification as the measure to make that determination. SWMC is currently Medicare certified and Medicaid eligible. The department recognizes that for this type of project (level III services), the Medicare eligible patients will not be using the service. However, some private pay insurance companies may require a facility to be Medicare certified and Medicaid eligible before making payment for other eligible patients.

The Charity Care Policy confirms that all residents of the service area including low-income, racial and ethnic minorities, handicapped and other underserved groups currently have access to healthcare services through SWMC and any of its affiliates. The policy also includes the process one must use to access charity care at SWMC. [source: Application, Appendix 12]

For charity care reporting purposes, the OHPDS, divides Washington State into five regions: King County, Puget Sound (less King County), Southwest, Central, and Eastern. SWMC is one of 13 hospitals located within the Southwest Region. According to 2002-2004⁸ charity care data obtained from OHPDS, SWMC has historically provided an average of charity care comparable to the Southwest regional average. SWMC's most recent three-year (2002-2004) average percentage of charity care for gross and adjusted revenues are 1.54% and 2.70%, respectively. The 2002-2004 average for the Southwest Region is 1.49% for gross revenue and 3.19%, for adjusted revenue. [source: OHPDS 2002-2004 charity care summaries] SWMC's pro formas and current charity care policies both indicate that the hospital will provide charity care at an average of 2.03% gross revenue and 4.91% adjusted revenues. These percentages indicate that SWMC intends to provide charity care at a percentage slightly higher than the most recent three-year regional average. [source: January 11, 2006, supplemental information, pp15-16]

The department concludes that approval of this project would not negatively affect patient access to the hospital, and SWMC's proposed level III services would be available to all residents of the service area. This sub-criterion is met.

B. Financial Feasibility (WAC 246-310-220)

Based on the source information reviewed, the department determines that the applicant has not met the financial feasibility criteria in WAC 246-310-220.

(1) The immediate and long-range capital and operating costs of the project can be met.

To analyze short- and long-term financial feasibility of hospital projects and to assess the financial impact of a project on overall facility operations, the department uses financial ratio analysis. The analysis assesses the financial position of an applicant, both historically and prospectively. The financial ratios typically utilized are 1) long-term debt to equity ratio; 2) current assets to current liabilities ratio; 3) assets financed by liabilities ratio; 4) total operating expense to total operating revenue ratio; and 5) debt service coverage ratio. If a project's ratios are within the expected value range, the project can be expected to be financially feasible.

For the SWMC project, the only ratios that apply are the long-term debt to equity ratio and the total operating expense to total operating revenue ratio. The remaining ratios are more appropriate to evaluate when an applicant intends to finance a project from an outside source. This project has already been funded through a \$2.4 million philanthropic donation. [source: OHPDS analysis, p2] Table

⁸ Year 2005 charity care data is not available as of the writing of this evaluation.

4 below shows the two applicable ratios for this project, in the first three years of operation for the hospital as a whole, with the level III NICU, and the Office of Hospital and Patient Data Systems (OHPDS) year 2004 financial ratio guidelines for hospital operations. [source: OHPDS analysis, pp2-3]

Table 4
Southwest Washington Medical Center's Projected Financial Ratios

Financial Ratio	OHPDS Guideline		SWMC Current Year 2004	Year 1 2008	Year 2 2009	Year 3 2010
Long Term Debt to Equity	0.530	* Below	0.250	0.493	0.439	0.382
Total Operating Expense to Total Operating Revenue	0.969	* Below	0.942	0.953	0.904	0.875

* = a project is considered more feasible if the ratios are above or below the value/guideline as indicated

After reviewing the financial information provided by SWMC, staff from OHPDS stated the following:

"The ratios are appropriate for a project like this. Southwest Washington Medical Center has had an average financial foundation in the past and I do not see this changing in the near future." [source: OHPDS analysis, pp2-3]

In addition to the projected ratios above, OHPDS also prepared a summary of SWMC's Statement of Operations for years 2008 through 2010 with the proposed level III services. [source: December 29, 2004, supplemental responses, Exhibit 5, Schedule C] A summary of the Statement of Operations is shown in Table 5 below.

Table 5
Southwest Washington Medical Center's Level III NICU Projected Statement of Operations

	Year One (2008)	Year Two (2009)	Year Three (2010)
# of Admissions	168	173	178
# of Patient Days	1,848	2,076	2,163
Average Length of Stay	11	12	12
Net Revenue*	\$ 6,570,069	\$ 7,453,850	\$ 8,166,303
Total Expense	\$ 5,320,517	\$ 5,998,295	\$ 6,484,581
Net Profit or (Loss)	\$ 1,249,552	\$ 1,455,555	\$ 1,681,722
Net Revenue per patient day	\$ 3,555.23	\$ 3,590.49	\$ 3,775.45
Total Expenses per patient day	\$ 2,879.07	\$ 2,889.35	\$ 2,997.97
Net Profit or (Loss) per patient day	\$ 676.16	\$ 701.14	\$ 777.48

*Includes deductions for bad debt and contractual allowances

As noted in Table 5 above, SWMC projects a net profit for its level III services in its first three years of operation. The pro forma expenses for the level III services include allocated costs. These costs represent the level III services' fair share of hospital non-revenue producing expenses (such as administration). With these costs included, operating revenues are still expected to exceed operating expenses. Therefore, the department concludes that SWMC would be able to meet its short and long term financial obligations and capital and operating costs of the project would be met. This sub-criterion is met.

- (2) The costs of the project, including any construction costs, will probably not result in an unreasonable impact on the costs and charges for health services.

OHPDS also compared SWMC's costs and charges to the year 2004 statewide average and determined that they are reasonable. [source: OHPDS analysis, p3]

As previously stated, the capital expenditure for the addition of level III services at SWMC is projected to be \$50,000, which includes only the application fees for submission of this project. [source: Application, p29] Table 6 below shows a breakdown of the fees for the project.

Table 6
Southwest Washington Medical Center's Capital Cost Breakdown

Total Capital Expenditure	\$ 50,000
Gross Square Footage	5,420
Level III Beds	18
Construction Cost per Gross Square Foot	\$ 9.23
Total Expenditure Cost per Unit	\$ 2,778.78

The applicant will adhere to the latest building codes for construction and energy conservation. After reviewing the construction costs above, staff from OHPDS concluded that the costs are within past construction costs reviewed and are appropriate. [source: OHPDS analysis, p4]

However, in the need section of this evaluation, the department concluded that the applicant failed to demonstrate that existing facilities are not available to meet the future need for level III services. Given that the project is not necessary, the department also concludes that the costs of this project may result in an unreasonable impact on the costs and charges for health services in the community. This sub-criterion is not met.

- (3) The project can be appropriately financed.

As stated in the project description portion of this evaluation, SWMC plans to co-locate its proposed level III services with its existing level II services. This co-location requires no further modifications since the special care nursery (level II space) was recently remodeled.

The capital expenditure for the addition of level III services at SWMC is projected to be \$50,000, which includes \$23,494 for consultant fees and \$26,506 for CN application fees. [source: Application, p29] The \$50,000 was donated to SWMC through its fundraising efforts.

Based on the source of funding for the project, the department concludes that the capital costs for this project will have no affect on the hospital's reserves, total assets, total liability, or general financial health. The proposed financing is appropriate, and this sub-criterion is met.

C. Structure and Process (Quality) of Care (WAC 246-310-230)

Based on the source information reviewed, the department determines that the applicant has not met the structure and process (quality) of care criteria in WAC 246-310-230.

- (1) A sufficient supply of qualified staff for the project, including both health personnel and management personnel, are available or can be recruited.

As stated in the project description portion of this evaluation, SWMC's proposed level III services will be offered in conjunction with its existing level II services. With the co-location of the services, SWMC anticipates adding only 3 FTEs to its existing complement of level II FTEs. SWMC indicates any impact on staff would be a direct result of increased patient volumes, and staff would be adjusted as appropriate to meet the care delivery needs. [source: Application, pp33-34]

Based on the projections shown in Table 2 on page 7 of this evaluation, SWMC projected the FTE increase for the level III services in the first three years of operation shown in Table 7 below. [source: January 11, 2006, supplemental information, p25]

Table 7
Southwest Washington Medical Center's Current and Projected Number of FTEs

Staff	Current-Level II	Increase-Level III	Total FTEs
Neonatalogist	1.0	1.5	2.5
Neonatal nurse practitioner	4.5	0.0	4.5
Nurse Manager perinatal	1.0	0.0	1.0
CNAs	4.2	0.0	4.2
Nurse Educator/clinical	1.0	0.0	1.0
Medical Social Worker	1.0	0.0	1.0
Respiratory Therapists	4.2	0.0	4.2
Dietician	0.5	0.5	1.0
Pharmacist	2.0	1.0	3.0
Total FTEs	19.4	3.0	22.4

As shown in Table 7 above, SWMC anticipates the establishment of level III services would result in a small increase of FTEs. Within the application, SWMC does not address its process for recruiting additional staff, however, because of the small number of FTEs identified above, the department would expect SWMC would not have difficulty recruiting staff for the proposed level III services. [source: Application, p33]

In addition to the staff identified in Table 7 above, SWMC anticipates recruiting the key medical staff and other providers for the level III services recommended in the Washington State Perinatal Levels of Care staffing guidelines. These key medical staff positions are further evaluated in conjunction with the department's evaluation of the project's conformance with the Washington State Perinatal Levels of Care guidelines shown below.

Washington State Perinatal Levels of Care Guidelines

In addition to the structure and process of care criteria found under WAC 246-310-230, the department uses the standards of care guidelines outlined in the Washington State Perinatal Levels of Care Criteria as guidance in evaluating this project. The guidelines, adopted by the Perinatal Advisory Committee on February 2005, offer recommendations on facility and staffing standards for level III services. Within the guidelines, level III services are separated into A, B, and C -- with A being the least intensive of level III services and C as the most intensive. The Perinatal Levels of Care Criteria recommend that an applicant be providing the previous level of services before applying for

the next higher level. For this application, SWMC should already be providing level I--basic OB services and level II-intermediate OB and neonatal services (both A and B), before applying for level III services. Within its Certificate of Need application, and verified by OHPDS CHARS data, SWMC meets this recommendation.

SWMC provided a comparison chart as verification and documentation that its proposed level IIIA services would meet or exceed the advisory committee's recommended guidelines. Given that SWMC does not propose to provide services beyond level IIIA (i.e. IIIB or IIIC), the department will compare this project using level IIIA guidelines. [source: Application, Appendix 10] The chart beginning on the following page summarizes the guidelines and comparison.

Southwest Washington Medical Center and Perinatal Levels of Care Criteria Comparison

GUIDELINE	SWMC
General Function	
<u>All Level IIB functions plus:</u> <u>Level IIIA-</u> <ul style="list-style-type: none"> • Diagnosis and management of selected pregnancies and neonates > 28 weeks gestation and > 1,000 grams • Care of severely ill neonates requiring mechanical ventilation • Minor surgical procedures such as central venous catheter or inguinal hernia repair • May be a state contracted regional perinatal center • Establishment of a perinatal database for quality improvement and outcomes monitoring 	All Level I and II functions plus: <ul style="list-style-type: none"> • The first level IIIA baby projected for January of 2007.
Neonatal Patients: Services and Capabilities	
<u>Level IIB patients and services plus:</u> <u>Level IIIA-</u> <ul style="list-style-type: none"> • Infants of > 28 weeks gestation and > 1,000 grams • Severely ill neonates at risk for requiring mechanical ventilation • Capabilities for prolonged mechanical ventilations • Capabilities for minor surgical procedures such as central venous catheter or inguinal hernia repair • Average Daily Census (ADC) of at least 10 level II/Level III patients. 	<u>Level IIB patients and services plus:</u> <ul style="list-style-type: none"> • Level IIIA in January 2007 • Infants of \geq 28 weeks gestation and > 1000 grams • Initiating CPAP and short-term ventilation in FY 2006. [Please see neonatologist timelines included with the CON application] • SWMC mechanical ventilation and minor surgical procedures such as CVP • OHSU for inguinal hernia repair • Currently meeting level II census at over 4 patients; will exceed 10 level II and III infants in FY 2010

GUIDELINE	SWMC
Obstetrical Patients: Services and Capabilities	
<p><u>Level IIB patients and services plus:</u> <u>Level IIIA</u></p> <ul style="list-style-type: none"> selected complicated pregnancies > 28 weeks gestation and estimated birthweight more than 1,000 grams Capabilities include: immediate cesarean delivery Capabilities include maternal intensive care 	<p><u>Level IIB patients and services plus:</u></p> <ul style="list-style-type: none"> Infants of ≥ 28 weeks gestation and > 1000 grams <p>ACOG guidelines followed. Care by SWMC OB medical staff and referral if required</p> <ul style="list-style-type: none"> Immediate cesarean delivery on site Maternal intensive care on site or by referral as appropriate per guidelines
Patient Transport	
<p>All hospitals demonstrate capabilities to stabilize and initiate transport of patients in the event of unanticipated maternal-fetal newborn problems that require care outside the scope of the designated level of care. Access to return transport services may be a necessary capability for Level IIIA and Level IIB intensive care nurseries.</p> <p>Transport patients:</p> <ul style="list-style-type: none"> Who are anticipated to deliver a neonate of earlier gestational age than appropriate for the facility's designated level of care in accordance with the law and should not transport if the fetus or mother is unstable or delivery is imminent. Whose illness or complexity requires services with a higher level of care than provided at the admitting facility. For neonatal transport, refer to AAP reference titled, "Guidelines for Air and Ground Transport of Neonatal and Pediatric Patients." <p>A hospital that transports patients to a higher level of care should:</p> <ul style="list-style-type: none"> Demonstrate on-going relationships with referral hospital(s) for education, immediate consultation, urgent transport facilitation, and quality assurance Establish a written policy and procedure for maternal and neonatal 	<p>Currently SWMC has established relationships for transport of neonates to OHSU, Providence St. Vincent, and Legacy Emmanuel in Portland, Oregon. SWMC also has a patient policy in place with Legacy Salmon Creek in Clark County.</p> <p>Established medical staff and interdisciplinary review through Maternal Child Performance Improvement Committee, OB Committee, and Pediatric Committee.</p>

<p>transport that includes an established triage system for identifying patients at risk who should be transferred to a facility that provides the appropriate level of care</p> <ul style="list-style-type: none"> • Establish guidelines that ensure a provider's continuing responsibility for and care of the patient until transport team personnel or receiving hospital personnel assume full responsibility for the patient. <p>A hospital that accepts maternal or neonatal transports in order to provide a higher level of care than is offered at the referral hospital, should:</p> <ul style="list-style-type: none"> • Participate in perinatal and /or neonatal case reviews at the referral hospital • Collaborate with state contracted perinatal center for coordinating outreach education • Maintain a 24 hr/day system for reliable, comprehensive communication between hospitals for immediate consultation, initiation, and approval of maternal and newborn transports • Provide referring physicians with ongoing communication and recommendations for ongoing patient care at discharge. 	
Medical Director	
<p><u>Obstetrics:</u> board certified in maternal-fetal medicine</p> <p><u>Nursery:</u> board-certified in neonatology</p>	<p>Perinatologist contract under development</p>

GUIDELINE	SWMC
Medical Providers	
<p><u>Level IIA staff plus:</u> <u>Obstetrics</u> Immediate availability of an obstetrician with demonstrated competence in the management of complicated labor and delivery patients.</p> <p><u>Newborn:</u> Immediate availability of neonatologist, pediatrician, or neonatal nurse practitioner with demonstrated competence in the management of severely ill neonates, including those requiring mechanical ventilation</p>	<p>Expanding neonatal nurse practitioner coverage to 24/7 coverage in FY 2006</p>
<p><u>Level II staff plus:</u> <u>Obstetrical</u> Anesthesiologist or nurse anesthetist immediately available</p> <p><u>Pediatric</u></p> <ul style="list-style-type: none"> • Echocardiography services with written protocols for pediatric cardiology consultation, including videotape interpretation • Complete range of genetic diagnostic services and genetic counselor on staff; referral arrangement for geneticist and diagnostics per written protocol • Arrangement of perinatal pathology services. 	<p>24/7 coverage in department at SWMC</p> <p>SWMC staff</p> <p>SWMC and referral to outside laboratory if required</p>
Nurse:Patient Ratio	
<p>Staffing parameters should be clearly delineated in a policy that reflects (a) staff mix and ability levels; (b) patient census, intensity, and acuity; and (c) plans for delegation of selected, clearly defined tasks to competent assertive personnel. It is an expectation that allocation of personnel provides for safe care of all patients in a setting where census and acuity are dynamic (ref 3)</p>	<p>Will continue to meet guidelines for staffing</p>

<p>Intrapartum:</p> <ul style="list-style-type: none"> • 1:2 patients in labor • 1:2 induction or augmentation of labor • 1:1 patients in second stage labor • 1:1 patients with medical or obstetric complications • 1:1 coverage for initiating epidural anesthesia • 1:1 circulation for cesarean delivery <p>Antepartum/postpartum</p> <ul style="list-style-type: none"> • 1:6 patients without complications • 1:4 recently born neonates and those requiring close observation • 1:3-4 normal mother-baby couplet care • 1:3 antepartum/postpartum patients with complications but in stable condition • 1:2 patients in post-op recovery <p>Newborns</p> <ul style="list-style-type: none"> • 1:6-8 neonates requiring only routine care* • 1:4 recently born neonates and those requiring close observation • 1:3-4 neonates requiring continuing care • 1:2-3 neonates requiring intermediate care • 1:1-2 neonates requiring intensive care • 1:1 neonates requiring multisystem support • 1:1 or greater unstable neonates requiring complex critical care <p>*Reflects traditional newborn nursery care. A nurse should be available at all times, but only one may be necessary, as most healthy neonates will not be physically present in the nursery. Direct care of neonates in the nursery may be provided by ancillary personnel under the nurse's direct supervision. Adequate staff is needed to respond to acute and emergency situations. The use of assistive personnel is not considered in the nurse: patient ratios noted here.</p>	
---	--

GUIDELINE	SWMC
Nursing Management	
<p>Same as Level I plus:</p> <ul style="list-style-type: none"> Advanced degree is desirable 	<p>Marcia Tolmasoff is the nurse manager of Perinatal services.</p> <p>In addition a FT nurse manager will join the team in FY 2006</p>
Support Providers: Pharmacy, Nutrition/Lactation and OT/PT	
<p><u>Pharmacy services</u> same as Level IIB</p> <p><u>Nutrition/Lactation</u> At least one registered dietitian/nutritionist who has special training in perinatal nutrition and can plan diets that meet the special needs of high-risk mothers and neonates</p> <p><u>OT/PT</u> Provide for inpatient consultation and outpatient follow-up- services</p>	<p><u>Pharmacy services</u> Will meet guidelines [see also FTE table in the application]</p> <p><u>Nutrition/Lactation</u> Will meet guidelines [see also FTE table in the application]</p> <p><u>OT/PT</u> SWMC staff and referral as needed</p>
Support Providers: Social Services/Case Management, Respiratory Therapy, Nurse Educator/Clinical Specialist	
<p><u>Social Services/case management</u> Level IIB services plus: At least one full-time licensed MSW (for every 30 beds) who has experience with socioeconomic and psychosocial problems of high-risk mothers and babies, available 7 days/wk and 24 hrs/day</p> <p><u>Nurse Educator/Clinical Nurse Specialist</u> A nurse educator or clinical nurse specialist with appropriate training in intensive neonatal or perinatal care to coordinate staff education and development. Those educators already in this position should be grandfathered in until post-graduate education is completed.</p> <p><u>Respiratory Therapy</u> Level IIB plus: 1 Respiratory Care Practitioner: 6 or fewer ventilated neonates with additional staff for procedures</p>	<p><u>Social Services/case management</u> Will meet guidelines [see also FTE table in the application]</p> <p><u>Nurse Educator/Clinical Nurse Specialist</u> Will meet guidelines.</p> <p><u>Respiratory Therapy</u> SWMC staff; will meet guidelines</p>

GUIDELINE	SWMC
X-Ray Ultrasound	
Level IIB services plus: Advanced level ultrasound available to Labor & Delivery and Nursery on-site and on a daily basis	SWMC staff
Laboratory and Blood Bank Services	
<u>Laboratory</u> Comprehensive services available 24 hrs/day	<u>Laboratory</u> SWMC staff
<u>Blood Bank</u> Blood bank technician on-call and available w/n 30 minutes for performance of routine blood banking procedures	<u>Blood Bank</u> SWMC staff
Provision for emergent availability of blood and blood products	

In addition to the comparison chart provided on the previous pages, SWMC also included the following documents:

SWMC Special Care Nursery Functional Plan [source: Application, Appendix 3]

This document addresses the rationale and timelines associated with SWMC's remodel and expansion of the special care nursery. SWMC also included a list of required equipment for the level II and III services (Appendix 4 of the application).

SWMC Level of Care Implementation Plan Timeframe [source: Application, Appendix 6]

This document outlines the timelines associated with implementation of its proposed level III services.

Administrative Services Agreement [source: November 18, 2005, supplemental information, pp10-25]

Between SWMC and OHSU and OHSUMG identifies:

- anticipated roles and responsibilities for all three entities;
- an implementation date for the existing level II services (May 1, 2005);
- reference to incorporation of the proposed level III services; and
- job description/administrative services information for the medical director, including compensation; [Exhibits A, B, & C of the Agreement].

Policy/Procedure for Admission to Special Care Nursery [source: November 18, 2005, supplemental information, p34]

This document is currently used for SWMC's level II services, and incorporates references to any level III services if approved.

Policy/Procedure for Transport to Level III Facility [source: November 18, 2005, supplemental information, p36-43]

This document outlines the process currently used by SWMC, in collaboration with OHSU and OHSUMG, for transporting level III patients to a level III provider. It does not identify the facility where SWMC transfers its patients.

Patient Transfer Agreement between SWMC and Legacy Salmon Creek Hospital [source: January 19, 2006, supplemental information, pp1-6]

This executed transfer agreement outlines the roles and responsibilities for both SWMC and LSCH.

It is clear from the documentation provided above that SWMC has already begun collaboration with OHSU and OHSUMG for its existing level II services and anticipates incorporation of level III services soon after CN approval. SWMC asserts that a collaborative level III service will enhance the on-site management of level III patients SWMC and minimize the transport of level III patients to Portland, Oregon. The department acknowledges there are some inherent risks with transporting level III patients; however, as a tertiary level health service, such transfers are expected. The department determined LSCH has the capacity to accommodate SWMC level III patients, and SWMC provided no documentation to demonstrative why they have elected not to transport to the nearest available facility.

However, based on the information provided by SWMC in its application and supplemental documentation, the department concludes that, if approved, SWMC's level III project would be consistent with the Washington State Perinatal Levels of Care guidelines. As a result, this sub-criterion is met.

- (2) The proposed service(s) will have an appropriate relationship, including organizational relationship, to ancillary and support services, and ancillary and support services will be sufficient to support any health services included in the proposed project.

This sub-criterion was extensively evaluated within the sub-criterion above, and is determined to be met.

- (3) There is reasonable assurance that the project will be in conformance with applicable state licensing requirements and, if the applicant is or plans to be certified under the Medicaid or Medicare program, with the applicable conditions of participation related to those programs.

As stated in the project description portion of this evaluation, in addition to the acute care hospital, SWMC operates a Medicare certified hospice agency, known as Hospice Southwest, and Hospice Southwest operates a 20 bed hospice care center. Both facilities are also located in the city of Vancouver. As part of its review, the department must conclude that the proposed level III services would be provided in a manner that ensures safe and adequate care to the public⁹. To accomplish this task, the department reviews the quality of care compliance history for all healthcare facilities owned, operated, or managed by SWMC. Since year 2000, the Department of Health's Office of Health Care Survey (OHCS), which surveys hospitals within Washington State, has completed two compliance surveys for the hospital, and three surveys each for the home health, hospice, and hospice care center.¹⁰ The surveys revealed minor non-compliance issues typical of the healthcare facility, and

⁹ WAC 246-310-230(5)

¹⁰ Hospital surveys conducted in 2003 and 2004, home health, hospice, and hospice care center surveys conducted in 2003, 2004, and 2005.

SWMC submitted and implemented plans of correction for the non-compliance issues within the allowable response time. [source: compliance survey data provided by Office of Health Care Survey]

Based on SWMC compliance history, the department concludes that there is reasonable assurance that the hospital would continue to operate in conformance with state and federal regulations with the addition of level III services. This sub-criterion is met.

- (4) The proposed project will promote continuity in the provision of health care, not result in an unwarranted fragmentation of services, and have an appropriate relationship to the service area's existing health care system.

In response to this criterion, SWMC indicates that providing level I through IIIA services to infants in one setting promotes continuity of care by enabling one team of providers to serve the needs of neonates with one standard of care and without a break in care due to transfer. Further, SWMC will use the Vermont Oxford information system to assure quality outcomes. SWMC also states it intends to use its Maternal Child Performance Improvement Committee to ensure the preservation and improvement of the quality, safety, and efficiency of patient care provided to mothers and neonates. [source: Application p 33]

The above response provided by SWMC addresses continuity of care for SWMC, however, continuity of care is not limited by a facility. Depending on the patient's needs, continuity of care may include transport of the patient to the most appropriate provider. For tertiary services, continuity of care means a hospital's ability and willingness to triage and transport as necessary to the most appropriate tertiary provider. For level III patients, this could mean that the patient would be transported to a physician or physician group who has not previously seen the patient. In this case, continuity of care also means that the referring hospital provides specific patient information and documentation to the receiving facility. Additionally, continuity of care also includes the communication and sharing of patient information between physicians in different facilities or physicians within the same facility. Further, with a tertiary program where there is a direct connection among sufficient patient volumes and provider effectiveness, quality of service, and improved outcomes of care, the department concludes that the establishment of a quality provider in this health care service is far more critical than patient, family, or physician convenience.

Based on this information, the department must reasonably conclude that the other level III facility operating in Clark County has capacity to serve the patients within the service area. Therefore, the department concludes that approval of this project has the potential of fragmentation of level III services within the service area, and this sub-criterion is not met.

- (5) There is reasonable assurance that the services to be provided through the proposed project will be provided in a manner that ensures safe and adequate care to the public to be served and in accord with applicable federal and state laws, rules, and regulations.

This sub-criterion is addressed in sub-section (3) above and is considered met.

D. Cost Containment (WAC 246-310-240)

Based on the source information reviewed, the department determines that the applicant has not met the cost containment criteria in WAC 246-310-240.

(1) *Superior alternatives, in terms of cost, efficiency, or effectiveness, are not available or practicable.*

Before submitting this application, SWMC considered and rejected three alternatives. Below is a summary of the alternatives and SWMC's rationale for rejecting them. [source: Application, pp35-37; November 18, 2005, supplemental information, pp117-118]

OPTION 1: Do nothing or status quo

This alternative was rejected by SWMC because it has already remodeled its special care nursery to accommodate the evolving standard of maternal fetal medicine. SWMC has already entered into a medical director contract with OHSUMG and is finalizing a professional services contract. SWMC states the community will benefit from SWMC's new model of care through improved access to a broader array of neonatal services and through improved continuity of care by decreasing the breaks in care related to transferring infants to another medical center. SWMC states that remaining as a level II provider would result in lost opportunities for additional improvement to access to services and continuity of care for families of neonates requiring level III services. Finally, SWMC states that the financial modeling shows that remaining as a level II provider would result in ongoing market share losses at SWMC that would degrade all of the perinatal services at the hospital.

OPTION 2: Develop an NICU level III service exceeding level IIIA capabilities

While this alternative was rejected by SWMC, it is considered by SWMC to be a viable future alternative. Level IIIB services would require the collaboration of level III and level II providers in a broad service area. SWMC states that a Certificate of Need is required to expand its services from level II to level III, however, if this project is approved, expansion from level IIIA to IIIB does not specifically require new approval. SWMC recognizes that under the level of care guidelines, the additional support services recommended to be provided on site for a level IIIB program require Certificate of Need approval. For example, pediatric heart surgery.

OPTION 3: Develop a collaborative agreement between SWMC and other level III providers within Clark/Skamania service area

Within the application, SWMC acknowledges that the only other provider in the Clark/Skamania service area is Legacy Salmon Creek located in Clark County. Under this option, level III patients would be transferred from SWMC to Legacy Salmon Creek. SWMC identified the following significant issues with this alternative.

- Legacy Salmon Creek has insufficient capacity to accommodate the projected need for both level II and all level III newborns for the Clark-Skamania area. This would require transfer of newborns to Portland area hospital, thus not obtaining the expected 95% retention standard as used in Table 10 of the [SWMC] Certificate of Need application.
- Legacy Health System in its Certificate of Need application response to questions indicated that the OFM [Office of Financial Management] mid-range population forecast was too conservative underestimating bed requirements. SWMC concurs.
- There is no level III provider in the Cowlitz-Wahkiakum area. SWMC currently experiences inflow for neonatal services from this area as well as inflow from Portland.

- Projections in the Certificate of Need application show that there will be future need for additional capacity even with SWMC and Salmon Creek capacity both on line.
- SWMC services for level II infants will be more expensive on a cost per unit of service basis since most of the costs associated with level II and level III services are concentrated at level II.
- SWMC will experience a substantial reduction in margin necessary to continue to underwrite its commitment to providing quality perinatal care to underserved women. Providing a comprehensive level of care is a key factor in retaining a payor mix and scope of services that offsets the losses associated with SWMC's commitment to provide care to underserved women.

Rather than the three alternatives above, SWMC chose to establish its level III services in support and in conjunction with OHSU and OHSUMG, hence this application. SWMC indicates that it has demonstrated need for an additional level III provider in the service area, and this alternative would promote system efficiencies in the delivery of level III services. Some of those efficiencies include:

- reduced transportation costs for families; and
- staff efficiencies at SWMC by using scarce resources, neonatologists and neonatal nurse practitioners more effectively.

SWMC states that the alternative to this project is to continue to rely on Portland facilities, which increases patient and family transportation costs significantly and place stresses on Portland area capacity. Finally, SWMC asserts that approval of this project will allow the hospital to continue its vital role as the primary provider of other maternal, neonatal, and pediatric services to the medically indigent in the service area. [source: Application, p38]

It appears from the three options above, that SWMC chose the option of submitting this application based, in part, on concerns regarding SWMC's future as a primary provider of OB, neonatal, and pediatric services in the community. While the department understands SWMC's impetus for submission of this application, SWMC did not demonstrate need for a second level III provider in Clark County or that the existing provider is not available and/or accessible to meet the future need (WAC 246-310-210). Further, the department concludes that the application does not meet the criteria of financial feasibility (WAC 246-310-220), and structure and process of care (WAC 246-310-230). As a result, the department concludes that the community is best served at this time by one level III provider.

On the basis of these conclusions, the department concludes that approval of this project is not the best available alternate for the service area, and this sub-criterion is not met.